REMARKS

This Office Action Response is submitted in response to the outstanding non-final Office Action, dated January 19, 2006. Claims 1-3, 17-19, 23-25 and 29 are presently pending in the above-identified patent application.

In the outstanding Office Action, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement.

The presently claimed invention is directed to the characterization of phenotypes by gene expression patterns. Generally, the presently claimed invention applies a transformation to convert a probability distribution of gene expression signals in control samples to a uniform distribution, thereby allowing better comparisons between expression levels for genes.

The comments of the Examiner in forming the objection and rejections are acknowledged and have been carefully considered.

FORMAL REJECTIONS

As mentioned above, the Examiner rejected claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. In the final paragraph of page 3 of the Office Action, the Examiner asserts that the "specification does not teach how to derive a transformation that transforms gene expression signals."

Applicants respectfully assert that the specification does teach how to derive a transformation. For example, Applicants point to FIG. 4, where an exemplary transformation is shown. Furthermore, in connection with FIG. 4, on page 22, lines 1-11, of the specification, it is stated that,

> a possible shape for P^{-}_{g} [] is plotted along with four expression values from hypothetical phenotype cells *a*, *b*, *c*, and *d*: u_a, u_b, u_c and u_d.... [i]n order to minimize the probability of finding random clusters in the control set, a metric must be chosen such that u_c and u_d would be considered further away than u_a and u_b.... [t]he present invention renormalizes the expression axis so that the distance between two points on the new axis is equal to the integral of the $P^{-}_{g}(u)$ in the previous coordinate system. This is accomplished by defining a new variable v obtained by transforming the original variable u with the non-linear

transformation of Equation (1). (Emphasis added).

The specification teaches that the "transformation may be thought of as a non-linear similarity metric." Page 14, lines 15-16. Therefore, the emphasized language above teaches how to derive a transformation that transforms gene expression signals.

In the first paragraph of page 4 of the Office Action, the Examiner asserts that the "instant claims are not drawn to comparison of any control transformation for phenotypes or comparison with unhealthy cells to determine gene expression patterns. It is unclear in the instant claims how one is to use a uniform distribution of unknown gene expression signals."

Applicant respectfully asserts that the Examiner is confusing the language of the specification (page 6, beginning line 21) that preceded the comment above in the Office Action. Unknown gene expression signals are not used to determine gene expression patterns. Rather, to determine gene expression patterns, what is taught is

> to take an initial set of expression data for one phenotype (generally called the control set and containing information from healthy cells) and to determine transformations from this data. The transformations are applied to a set of expression data from another phenotype (generally called the phenotype set and containing information from unhealthy cells). The transformed set of data is used to determine gene expression patterns that are characteristic of the phenotype. Page 6, lines 2-26, of the specification. (Emphasis added).

The use of unknown gene expression signals corresponds primarily the withdrawn claims relating to the classification of samples based on gene expression patterns. For example, beginning on page 6, line 27, of the specification, it is stated that,

> [n]ew expression data from samples that have an unknown genetic makeup are compared with the gene expression patterns. Based on this comparison, the new samples are classified as belonging to one of the two phenotypes.

Furthermore, in the discussion of the *In re Wands* factors for "undue experimentation," the Examiner failed to credit the presence of working examples in the specification, beginning on page 23 of the specification.

Given the above remarks, Applicants respectfully request reconsideration and withdrawal

of the rejections of claims 1-3, 17-19, 23-25 and 29 under 35 U.S.C. §112, first paragraph.

In view of the foregoing, Applicants submit that all of the pending claims, i.e., claims 1-3, 17-19, 23-25 and 29, are in condition for allowance and such favorable action is earnestly solicited.

If any outstanding issues remain, or if the Examiner has any further suggestions for expediting allowance of this application, the Examiner is invited to contact the undersigned at the telephone number indicated below.

The Examiner's attention to this matter is appreciated.

Respectfully submitted,

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